Remarks:

In light of the Amendment and Remarks filed on December 5, 2007, the Subject Application presently includes clams 1, 2, 4-8, 10, 12-20 and 32-34. Of these pending claims, claim 1 is the single independent claim. In the present Response, Applicants amend claims 1, 5, 6, and 14, and add new claim 53.

In the Office Action, the Examiner notes a correction he made to the Form PTO/SB/08 submitted by Applicants on August 29, 2006. Applicants and the undersigned thank the Examiner for his correction of this error.

Applicants and the undersigned also express their gratitude to the Examiner for his consideration of Applicants' December 5, 2006 Amendment and Remarks and for withdrawing the previous basis for rejecting the Subject Application's claims.

Applicants address the Examiner's current objection and rejections in separate sections below.

1. **The Objection**

In the Office Action, the Examiner objects to claim 14 for the reason that it includes an informality. Specifically, the Examiner asserts that "weight percent" in claim 14 should be deleted. Applicants amend claim 14 herein to delete "weight percent".

2. **The Rejection under § 112**

The Examiner rejects claim 1 under 35 U.S.C. § 112, first paragraph, asserting that the following claimed subject matter is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention: "at least 0.05 weight percent aluminum, at least 5 ppm calcium, at least 5 ppm magnesium, and at least 5 ppm cerium." Applicants herein amend claim 1 to recite the upper limit of the ranges for these elements as was recited in dependent claims 12-15. Given that this amendment fully addresses the Examiner's § 112 rejection of claim 1, it also addresses the Examiner's § 112 rejection of dependent claims 2, 4-8, 10, 12-20, and 32-34.

3. The § 103(a) Rejection over Smith

The Examiner rejects claims 1-2, 4-8, 10, 12, 16-20, and 32-34 under 35 U.S.C. § 103(a) as having been obvious over Smith U.S. Patent No. 3,356,542 ("Smith"). The Examiner asserts that the alloy composition described in Smith "overlaps with the composition of the claimed invention." The Examiner further asserts that a prima facie case of obviousness exists because "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to select the claimed compositions of an alloy from the composition disclosed by Smith ... because Smith ... discloses the same utility (alloy wire) throughout the disclosed ranges."

The Examiner concedes that Smith does not specify whether the Smith alloy includes spherical oxide inclusions and is substantially free of titanium nitride and mixed metal carbonitride inclusions, as is recited in claim 1. Nevertheless, the Examiner concludes that (1) "the composition of titanium, nitrogen, and carbon within the [Smith] alloy can be non-existent", and (2) Smith discloses "arc melting and induction melting in a vacuum atmosphere as methods of preparing the [Smith] alloy, which would be substantially the same techniques of producing the alloys of the instant invention." Based on conclusions (1) and (2), which the Examiner notes have not yet been contradicted by evidence to the contrary, the Examiner concludes that "it would be expected that the alloys of Smith ... would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions."

Applicants traverse the Examiner's basis for rejecting the claims and submit that the rejections should be withdrawn for the following reasons.

The test for patentability under 35 U.S.C. § 103(a) requires that: the scope and content of the prior art be determined; the differences between the prior art and the claims at issue be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. *See* MPEP § 2141. Further, in order to properly formulate a rejection under § 103(a), all the claim elements and limitations must be taught or

suggested by the asserted prior art. *See, e.g.,* MPEP § 2143.03. Further still, in formulating a rejection under § 103(a), the Office must identify in an Office Action a rational basis why a person of ordinary skill in the art would have combined or modified the prior art elements in the manner claimed. *See* attached copy of May 3, 2007 Memo by Margaret A. Focarino, Deputy Commissioner for Patent Operations, to Technology Center Directors; *see also KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007) (a patent examiner must provide "an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate this review, this analysis should be made explicit."); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited with approval in *KSR)* ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")

In the Office Action, the Examiner contends that he has established a *prima facie* case that the invention recited in claim 1 would have been obviousness in light of Smith. Applicants disagree. First, as discussed below, Smith does not teach or suggest all of the elements and limitations of claim 1. Specifically, the alloy described in Smith would not have had a composition overlapping that recited in claim 1, and one having ordinary skill, at a time before the filing of the Subject Application, would not have been motivated to modify the composition described in Smith in a way to achieve the alloy composition recited in claim 1. Also, the alloy described in Smith would not have been "substantially free of titanium nitride and mixed metal carbonitride inclusions", as is recited in claim 1. Second, even assuming that the Examiner has established a *prima facie* case that the alloy of claim 1 would have been obvious over Smith, secondary considerations present here clearly shown that the claimed invention would not have been obvious.

Regarding the alloy disclosed in Smith, the sole reference to nitrogen and titanium contents in Smith is the following passage at Smith's col. 4, lines 69-72:

> It is critically important that the alloy composition contain no more than 0.05% of carbon, boron, oxygen, nitrogen, or beryllium, the total of these components being no more than 0.1%. Amounts greater than this, particularly amounts of carbon greater than that specified, will cause such embrittlement as to make the work-strengthening non-operable. It is particularly preferred to maintain the carbon content below 0.015% to insure adequate workability.
>
> The presence of aluminum, titanium and zirconium should be limited to no more than 2% each and to a total of no more than 4%. The presence of these elements up to the specified limits may impart some additional strengthening; amounts above those specified will not only affect the properties of the final product adversely, but may lower processability through such mechanisms as interstitial embrittlement and grain boundary second phase formation.

Smith does not describe an alloy including less than 30 ppm of nitrogen, as is recited in claim 1. Nor does Smith in any way suggest any benefit to limiting the nitrogen content of the Smith alloy to less than 30 ppm, or even to very minor amounts. The above passage of Smith merely describes an upper limit for nitrogen in the alloy. That limit is 0.05%, 500 ppm, a value that is more than 16 times greater than the critical 30 ppm value recited in claim 1. Even if it can be said that a teaching that the Smith alloy can withstand up to 500 ppm nitrogen inherently encompasses a lower limit of zero, that teaching would not be sufficiently specific to teach or suggest the specific range of less than 30 ppm nitrogen. It is the range of less than 30 ppm nitrogen that the inventors have discovered is critical to providing the improved performance of the alloys according to claim 1. *See* MPEP 2131 ("If the claims are directed to a narrow range, [and] the reference teaches a broad range, ... [i]t may be reasonable to conclude that the narrow range is not disclosed with 'sufficient specificity' to constitute an anticipation of the claims." (citing *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006)). The attached Declaration of Henry E. Lippard (the "Lippard Declaration") confirms that one having ordinary skill would not have read Smith to teach or suggest limiting nitrogen in the Smith alloy to less than 30 ppm.

In any case, as confirmed in the attached Lippard Declaration, the Smith alloy necessarily would have included at least 50 ppm nitrogen which, as is discussed in the Subject Application, is the minimum level of nitrogen found in a conventional MP35N alloy. Indeed, the alloy examples in Smith all are melted in open-air furnaces, without concern for atmospheric nitrogen. Although Smith does mention the possibility of melting the alloy under vacuum, it does not state or suggest that doing so is useful for the purpose of, or has any advantage in terms of, reducing levels of nitrogen in the alloy. Absent the motivation to take the extraordinary steps of the present inventors to limit nitrogen in the alloy of claim 1 to extremely low levels, less than 30 ppm, the alloy of Smith would include a significantly greater nitrogen concentration due to, for example, nitrogen in the raw materials and in the furnace atmosphere. Again, Smith does not describe or suggest any reason why one of ordinary skill would take the significant and costly steps to limit nitrogen in the Smith alloy to such extremely low levels of less than 30 ppm. Therefore, the Examiner's reference to the nitrogen range of Smith as "0-0.05" in the Table included in the Office Action does not accurately characterize the teaching of Smith. Absent restricting nitrogen content to less than 30 ppm, as is recited in claim 1, one also could not develop the microstructure that is specifically recited in claim 1.

More generally, the Examiner reaches a sweeping and unsupported conclusion that the very broad alloy composition he asserts Smith discloses would have rendered obvious the much narrower composition recited in claim 1. The inventors have discovered the alloy composition recited in claim 1 is critical to the alloy's significantly enhanced mechanical performance in certain surgical implant applications. Selecting that recited alloy composition out of the substantially broader composition the Examiner asserts Smith teaches amounts to no more than an impermissible hindsight reconstruction of the claimed invention. A consideration of the present invention's history may be helpful here. The story of how the present claimed invention was made, which is largely set out in the Subject Application and also is recounted in the attached Lippard Declaration, began with a long-felt but as-then unmet need for improved small

diameter MP35N alloy wire for use in the cardiac pacemaker lead industry and, more generally, in the surgical implant industry. The significant existing drawbacks of surgical implant-gauge wire produced from conventional MP35N alloy are discussed in paragraph 0003 of the Subject Application:

> Certain technical problems may be encountered during the manufacture of MP35N alloy for use in pacing leads and other surgical implant applications. In particular, problematic surface defects may appear when cold drawing the alloy to wire. When drawing the alloy to small gauge wire for use as pacing leads, for example, surface defects are most likely to develop during the late stages of the drawing process, when the wire approaches the 0.007 inch diameter final size typically used for such applications. Drawing-related surface defects are particularly problematic because they may appear after significant time and money are invested in the product. As the wire approaches small diameter, the surface defects may cause the wire to fracture during cold drawing. This results in lower process yields during production, which can significantly increase the cost of the wire. Pacing leads and other surgical implants formed from MP35N alloy wire having surgical defects also may have reduced fatigue resistance and may be susceptible to fracture. The resultant reduced service life may require premature replacement of the implant.

Against this backdrop, the present inventors set to work to identify and address the phenomenon underlying the industry-recognized sub-par mechanical performance of conventional MP35N wire. The present inventors discovered that titanium nitride and mixed metal carbonitride inclusions present in conventional MP35N alloys are problematic because they are generally large and have a cuboidal morphology that scores the surfaces of drawing dies used to make small-diameter wire from the alloy. It was the present inventors who initially discovered a link between the presence and morphology of these inclusions in conventional MP35N alloy and the mechanical performance of the alloy in certain surgical implant applications, such as in pacing leads. As explained in paragraph 0033-0034 of the Subject Application, the present inventors realized that the presence and morphology of the above-mentioned inclusions is the source of conventional MP35N alloy's poor mechanical performance:

> It has been determined that the poor performance of MP35N alloy during cold drawing and forging [relates] to the presence of large, hard titanium nitride (TiN) inclusions. Also, in MP35N alloys including relatively high nitrogen levels, large, hard cuboidal mixed metal carbonitride inclusions may form in the alloys. The mixed metal carbonitrides are principally titanium and chromium carbonitrides. The principal failure mechanism of the conventional MP35N alloy upon drawing and forging is fatigue initiation at the particulate inclusions. The TiN and mixed metal carbonitride inclusions may form during solidification of the alloy after melting, and the particles cannot be removed or broken up by the subsequent heat treatment or thermomechanical processing. Instead, it has been determined that the inclusions are retained in their as-cast size in the final product.
>
> The hard TiN and mixed metal carbonitride particles damage the drawing die during cold drawing of conventional MP35N material. Wire drawn through a damaged die may have surface defects in the form of scratches on the wire surface. Die damage and resulting wire surface defects significantly reduce yield. As the drawn wire becomes smaller in diameter, the nitride and carbonitride particles take up a larger portion of the wire cross-section and, therefore, weaken the material, thus creating fractures during drawing. The particles also act as stress raisers during fatigue loading and contribute to the initiation of fatigue cracks, which can result in the premature failure of the material and the associated device.

Thus, the present inventors determined that scoring of the drawing dies by the inclusions in the alloy produces surface defects on the drawn wire, which can cause the wire to break when further drawn or mechanically processed or, more critically, when subjected to fatigue over time in the body of a patient. The present inventors also concluded that the titanium nitride and mixed metal carbonitride inclusions themselves in conventional MP35N alloy wire can create points of localized stress in the drawn wires, resulting in or contributing to wire breakage during drawing or when in use implanted in the body of a patient.

Having made these discoveries, the present inventors set to work attempting to produce a modified form of the MP35N alloy that did not suffer from these deficiencies. The present inventors unexpectedly discovered that a modified MP35N-type alloy

composition that includes, *inter alia*, less than 30 ppm nitrogen, less than 0.7 weight percent titanium, and minor but critical amounts of at least one of aluminum, calcium, magnesium, and cerium has a microstructure that is substantially free of the problematic titanium nitride and mixed metal carbonitride inclusions and, instead, includes well-tolerated relatively small, generally spherical oxide inclusions. This substantial change in microstructure was unexpected and significant – the inventors observed that the spherical oxide inclusions in the modified alloy did not significantly score wire drawing dies, reducing the incidence of surface defects on the drawn wire, and also did not produce regions of substantially increased stress within the wire. This was not merely a slight adjustment to microstructure, but was a significant technical breakthrough that produced a fundamentally different alloy microstructure and directly addressed drawbacks that the inventors discovered were present in the existing alloy.

Moreover, as discussed in paragraphs 0075 to 0080 of the Subject Application, likely as a result of the foregoing microstructural changes, small-diameter wire produced from the alloy exhibits unexpected and substantially improved fatigue resistance relative to conventional MP35N alloy. For example, Table 9 of the Subject Application shows that at 100 ksi, a stress level similar to that to which pacing leads are subjected in service, wire formed from the alloy of the present invention withstood at least 797% the number of cycles in rotary beam fatigue testing than wire produced from conventional MP35N alloy. Also, the modified alloy was determined to have a fatigue endurance limit of between 100-110 ksi versus the 90 ksi limit of the conventional alloy. The significance of the substantial improvement in fatigue properties by the alloy recited in claim 1 cannot be overstated and could not have been predicted, even from the significant change in alloy microstructure achieved by the invention. This improvement in fatigue resistance is especially significant in light of the critical nature of application for cardiac pacemaker leads fabricated from small diameter MP35N wire. An end of a lead is inserted directly into the heart muscle and conducts current from the pacemaker to the heart, continuously regulating the heartbeat – as one can imagine, fracture of an implanted lead can have severe consequences, and it is of great importance (especially

to the patient) to increase the service lifetime of the leads as long as possible so as to postpone replacement surgery.

Accordingly, prior to the present inventors' discovery of the underlying reasons for the above-discussed failure mechanism, there existed no clear understanding of the deficiencies in microstructure of conventional MP35N alloy wire used in pacemaker lead wires and in other surgical implant applications that contributed to the sub-par performance of the wire. Because the problems inherent in conventional MP35N alloy were not known before being discovered by the present inventors, there would have existed no motivation or suggestion to modify the microstructure of the Smith alloy so that it substantially lacked titanium nitride and mixed metal carbonitride inclusions and, instead, included generally spherical oxide inclusions, as recited in claim 1. In addition, there would certainly have existed no motivation to take the specific steps, such as reducing nitrogen content to less than 30 ppm and making other modifications to alloy chemistry and processing, which the inventors discovered avoids the problematic microstructure present in conventional MP35N alloy. Moreover, the inventors' discoveries, once they set upon addressing the microstructural deficiencies they identified in MP35N alloy, were both unexpected and significant. They unexpectedly discovered that the alloy recited in claim 1, which includes very low levels of nitrogen, limited levels of titanium, and the addition of minor amounts of one or more of aluminum, calcium, magnesium, and cerium, substantially lacks problematic large cuboidal titanium nitride and mixed metal carbonitride inclusions. In addition, small diameter wire drawn from the claimed alloy exhibited a substantial and unexpected improvement in fatigue resistance, which would significantly improve wire yield and service lifetime in pacemaker lead and other surgical implant applications.

Returning to the specific rejection at hand, the Examiner has not established a case of obviousness since such a rejection requires that all the claim limitations are taught or suggested by the prior art. MPEP § 2143.03. Smith fails to disclose or in any way suggest limiting nitrogen in the alloy to the extremely low level of less than 30 ppm. Absent limiting nitrogen to these very low levels recited in claim 1, alloy microstructure

would not be substantially free of titanium nitride and mixed metal carbonitride inclusions. Smith also does not specifically teach or otherwise suggest a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions. Accordingly, Smith also does not teach or suggest an alloy having a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions and, instead, includes well-tolerated substantially spherical oxide inclusions, as is recited in claim 1.

The Examiner's rejection of claim 1 over Smith amounts to impermissible hindsight – the Examiner impermissibly concludes that the claimed invention would have been obvious based on the present inventors' revelation, in the Subject Application, that the invention recited in claim 1 provides significant advantages. *See KSR Int'l*, slip op. *at 17* ("A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments relying on *ex post* reasoning."); *Graham v. John Deere Co.*, 383 U.S.1, 36 (1966) (warning against a "temptation to read into the prior art the teachings of the invention in issue' and instructing the courts to "'guard against slipping into the use of hindsight'" (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1946)); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) ("It is difficult but necessary that the decisionmaker forget what he or she has been taught ... about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.")

Moreover, even assuming *arguendo* that the Examiner has established a *prima facie* case of obviousness based on Smith, secondary considerations present here clearly show that the invention recited in claim 1 was not obvious on a date just before the Subject Application was filed. MPEP § 2144.05 explains that the nonobviousness of overlapping ranges can be established by a showing that the claimed invention: (1) provides unexpected results; (2) addresses a long-felt and unmet need; and/or

(3) has met with commercial success. *See also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) ("evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness.) Each of these three secondary considerations is present here.

As discussed above and in the attached Lippard Declaration, the alloy recited in claim 1 addresses a long-felt and, up until the date the invention was made available, unmet need for small-diameter MP35N alloy wire for use in pacemaker leads and other surgical implants having substantially improved fatigue resistance.

As also discussed above and in the attached Lippard Declaration, small-diameter wire formed from the alloy of claim 1 has a unique and unexpectedly well-tolerated microstructure that provides unexpectedly and substantially improved fatigue properties relative to conventional MP35N wire. Evidence of the unexpectedly improved fatigue resistance of wire formed of the alloy recited in claim 1 also is presented in detail in the specification of the Subject Application, and the Examiner has not indicated whether he has considered that evidence. As required by MPEP § 716.01(a), "Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims." *See also In re Margolis*, 785 F.2d 1029 (Fed. Cir. 1986).

Finally, Applicants will be submitting a declaration of Robert J. Myers, Executive Vice President of Fort Wayne Metals Research Products Corporation, clearly showing that (1) small diameter wire produced from the alloy recited in claim 1 has enjoyed very substantial commercial success, and (2) the commercial success is directly attributable to the unexpected and substantial improvement in fatigue resistance of wire made according to the claims of the Subject Application. Mr. Myers is currently traveling overseas and will not return to the U.S. until September 4, and he was not available to sign the declaration in time to be submitted with this Response. The undersigned will be submitting Mr. Myers' declaration to the Examiner soon after he returns to the U.S.

Accordingly, the presence of these secondary considerations shows that the alloy recited in claim 1 would not have been obvious in view of Smith. It follows that rejected claims 2, 4-8, 10, 12, 16-20, and 32-34, which directly or ultimately depend from claim 1, also would not have been obvious over Smith. Accordingly, the Examiner should withdraw his rejection of claims 1-2, 4-8, 10, 12, 16-20, and 32-34.

The § 103(a) Rejection over Smith in view of Thielemann

The Examiner rejects claims 13 and 14 under 35 U.S.C. § 103(a) as having been obvious over Smith in view of Thielemann U.S. Patent No. 3,241,954 ("Thielemann"). Claim 13 is directed to the alloy of claim 1, further including 5 to 20 ppm calcium. Claim 14 is directed to the alloy of claim 1, further including 5 to 50 ppm magnesium. The Examiner concedes that Smith does not specify the levels of calcium and magnesium recited in claims 13 and 14, respectively, but concludes that Thielemann would have suggested adding those elements in the recite levels to the Smith alloy.

Initially, Applicants note that they have shown herein that the alloy recited in claim 1 of the Subject Application would not have been obvious over Smith. The addition of teachings from Thielemann does not remedy this. Therefore, it follows that Smith would not have suggested an alloy as recited in claims 13 and 14, which incorporates all of the limitations from claim 1. For that reason the present rejection of claims 13 and 14 should be withdrawn.

In addition, as supported by the attached Lippard Declaration, Thielemann is directed to alloys that differ significantly from the alloys described in Smith. For example, the Smith and Thielemann alloys differ in at least the following significant respects:

- Molybdenum: The Smith alloy includes 7-16% molybdenum. The Thielemann alloy lacks any appreciable level of molybdenum.
- Tantalum: The Smith alloy lacks any appreciable level of tantalum. The Thielemann alloy includes 4-16% tantalum.

- Tungsten: The Smith alloy lacks any appreciable level of tungsten. The Thielemann alloy includes 5-15% tungsten.
- Nickel: The Smith alloy includes 5-45% nickel. Thielemann specifically teaches that its alloy must not include more than 3.5% nickel (see col. 7, lines 5-33).
- Carbon: The Smith alloy includes no more than 0.05 % carbon. The Thielemann alloy includes 0.1-1.3% carbon, which is at least twice the level of carbon as in Smith.

As confirmed in the attached Lippard Declaration, these compositional differences are very significant, and it is not correct to say that, relative to Smith, Thielemann teaches "an analogous cobalt-base alloy". Instead, the alloy described in Thielemann differs so substantially in composition from Smith that one of ordinary skill would not look to Thielemann for teachings in any way pertinent or useful to advantageously modifying the Smith alloy. Viewed another way, given the very substantial compositional differences between the Smith and Thielemann alloys, one of ordinary skill would not perceive in the teachings of Thielemann any motivation or suggestion to modify the composition of the Smith alloy in any way.

Accordingly, the Examiner should withdraw his rejection of claims 13 and 14.

5. The § 103(a) Rejections over Smith in view of Crook

The Examiner rejects claim 15 over Smith in view of Crook U.S. Patent No. 4,353,742 ("Crook"). Claim 15 is directed to the alloy of claim 1, further including 5 to 50 ppm cerium. The Examiner concedes that Smith does not specify the cerium level recited in claim 15, but concludes that Thielemann would have suggested adding that element to the Smith alloy "to impart good oxidation resistance to the cobalt-base alloy at high temperatures."

Applicants have shown herein that the alloy recited in claim 1 of the Subject Application would not have been obvious over Smith. The addition of teachings from Crook does not remedy this. Therefore, it follows that Smith in view of Crook would not

have suggested an alloy as recited in claims 15, which incorporates all of the limitations from claim 1. Therefore, the present rejection of claim 15 should be withdrawn.

In addition, as supported by the attached Lippard Declaration, Crook is directed to alloys that differ significantly from the alloys described in Smith. For example, the Smith and Crook alloys differ in at least the following significant ways:

- Chromium: The Smith alloy includes 13-25% chromium. The Crook alloy includes 27-35% chromium.
- Boron: The Smith alloy includes no more than 0.05% boron. The Crook alloy may include up to 0.3% boron.
- Carbon: The Smith alloy includes no more than 0.05% carbon. The Crook alloy may include up to 2.25% carbon.

As confirmed in the attached Lippard Declaration, these compositional differences are significant, and it is not correct to say that, relative to Smith, Crook teaches "an analogous cobalt-base alloy". Rather, the Thielemann alloy differs so substantially in composition from Smith that one of ordinary skill would not look to Crook for teaching pertinent or useful to modifying the Smith alloy. Viewed another way, given the very substantial compositional differences between the Smith and Crook alloys, one of ordinary skill would not perceive in the teachings of Crook any motivation or suggestion to modify the composition of the Smith alloy in any way.

Accordingly, the Examiner should withdraw his rejection of claim 15.

6. New Claim 54

Applicants present a new claim 54 in this response. Claim 54 depends from claim 1, includes limitations from several of the pending claims, and also recites the transitional phrase "consisting of". Applicants submit that new claim 54 is fully supported by the Subject Application, does not add new matter, and is in condition for allowance.

Conclusion:

Applicants have made a diligent effort to fully respond to the Office Action and hereby traverse all rejections presented. Applicants respectfully submit that claims 1, 2, 4-8, 10, 12-20, and 32-34 of the Subject Application, as amended herein, and new claim 53 are in condition for allowance. Applicants respectfully request issuance of a Notice of Allowance at an early date. Applicants' present response should not in any way be taken as acquiescence to any of the specific assertions, statements, etc., presented in the Office Action not explicitly addressed herein. Applicants reserve the right to specifically address all such assertions and statements in subsequent responses

Respectfully submitted,

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MEMORANDUM

DATE: May 3, 2007

TO: Technology Center Directors

FROM: Margaret A. Focarino
Deputy Commissioner
for Patent Operations

SUBJECT: Supreme Court decision on *KSR Int'l. Co., v. Teleflex, Inc.*

The Supreme Court has issued its opinion in *KSR*, regarding the issue of obviousness under 35 U.S.C. § 103(a) when the claim recites a combination of elements of the prior art. *KSR Int'l Co. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 2007). A copy of the decision is available at http://www.supremecourtus.gov/opinions/06pdf/04-1350.pdf. The Office is studying the opinion and will issue guidance to the patent examining corps in view of the *KSR* decision in the near future. Until the guidance is issued, the following points should be noted:

(1) The Court reaffirmed the *Graham* factors in the determination of obviousness under 35 U.S.C. § 103(a). The four factual inquiries under *Graham* are:

(a) determining the scope and contents of the prior art;
(b) ascertaining the differences between the prior art and the claims in issue;
(c) resolving the level of ordinary skill in the pertinent art; and
(d) evaluating evidence of secondary consideration.

Graham v. John Deere, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

(2) The Court did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

(3) The Court rejected a rigid application of the "teaching, suggestion, or motivation" (TSM) test, which required a showing of some teaching, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the prior art elements in the manner claimed in the application or patent before holding the claimed subject matter to be obvious.

(4) The Court noted that the analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. The Court specifically stated:

> Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.

KSR, slip op. at 14 (emphasis added).

Therefore, in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.